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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,657	06/29/2001	Debra A. Timm	JOHNA.061A	9725

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 04/02/2002

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/897,657

Applicant(s)

TIMM ET AL.

Examiner

Jennifer Kolb Michener

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/29/2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 16, and those depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "applying said material with a bioactive coating on said material" is unclear. The phrasing implies that the material is applied to something, instead of that a coating is applied to a material. The claim could be interpreted as a method of applying two materials at the same time to an un-named substrate. From a reading of the specification, the "material" is the substrate. Examiner suggests the phrases "applying to said material a bioactive coating" or "applying a bioactive coating to said material" as more clear.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1762

4. Claims 1-5, 8, 11, 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikada et al. (U.S. Pat. 4,743,258).

Ikada teaches that polymers may be attached to the surface of a substrate material by graft polymerizing monomers to the surface via peroxide radicals formed in low temperature plasma discharge (col. 2, lines 51-65). The substrate of Ikada may be acrylonitrile-butadiene-styrene (col. 3, line 31). The coating material of Ikada may be polyvinyl alcohol or amides (col. 3).

While Ikada fails to specifically teach the source of the peroxide radicals, "peroxide" radicals are part of a relatively small class of chemicals containing a bond between two oxygens. Hydrogen peroxide is a well-known member of the class of peroxides useful in plasma operations. It would have been obvious to one of ordinary skill in the art to select hydrogen peroxide from the class of peroxides taught by Ikada with the expectation of successful results, in the absence of a showing of criticality.

It is Examiner's position that the graft polymerization process of Ikada would inherently result in sterilization of the substrate material and coating because the polymerization steps of Ikada involve the low-temperature peroxide plasma process as is required by the sterilization step of Applicant. Any differences in properties between the claimed invention and that of the prior art would be due process variables not claimed in the instant application.

5. Claims 1-5, 8, 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akagi et al. (U.S. Pat. 4,728,564).

Art Unit: 1762

Akagi teaches exposing a polyester substrate to peroxide radicals formed in a low temperature plasma discharge operation and to polymerizable monomers to effect polymerization of the monomers by a so-called peroxide process (col. 9, lines 53-60).

While Akagi fails to specifically teach the source of the peroxide radicals, "peroxide" is a small class of chemicals containing a bond between two oxygens. Hydrogen peroxide is a well-known member of the class of peroxides useful in plasma operations. It would have been obvious to one of ordinary skill in the art to select hydrogen peroxide from the class of peroxides taught by Akagi with the expectation of successful results, in the absence of a showing of criticality.

It is Examiner's position that the graft polymerization process of Akagi would inherently result in sterilization of the substrate material and coating because the polymerization steps of Akagi involve the low-temperature peroxide plasma process as is required by the sterilization step of Applicant. Any differences in properties between the claimed invention and that of the prior art would be due process variables not claimed in the instant application.

6. Claims 1, 3, and 5-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendriks (U.S. Pat. 5866113) in view of Spencer (U.S. Pat. 5,656,238).

Hendriks teaches graft polymerizing polymers, such as hydroxyethyl methacrylate or polyamides, and heparin onto medical devices made of materials such as collagen, bone, elastin, rubber, stainless steel, polyurethane, and ceramics (abstract; col. 6, lines 60-68; col. 7, line 35; col. 18, line 47).

Art Unit: 1762

While Hendriks teaches sterilization of the coated medical device by ethylene oxide, he fails to teach hydrogen peroxide plasma sterilization as a method of sterilizing the medical device.

Spencer teaches a method of sterilizing medical instruments with a low-temperature plasma of hydrogen peroxide.

Since Hendriks teaches sterilizing medical instruments with such a method as ethylene oxide and Spencer teaches sterilizing medical instruments using hydrogen peroxide, Spencer would have reasonably suggested the use of hydrogen peroxide sterilization as an alternative in the method of Hendriks. It would have been obvious to one of ordinary skill in the art to use the sterilization teachings of Hendriks in the method of Spencer as a suitable, effective, sterilization alternative to ethylene oxide with the expectation of similar, successful results.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Examiner cites Williams et al. for teaching that the same type of gas plasma may be used for cleaning, surface modification, and polymer deposition (col. 9, lines 50-55). Jacob et al. is cited for teaching that monomers may polymerize under the plasma conditions used to sterilize them. Ahlfors is cited for teaching hydrogen peroxide as a commonly used type of peroxide. Goldberg is cited for teaching a similar basic method as Hendriks, i.e., graft polymerization onto medical devices,

Aft Unit: 1762

followed by sterilization. In specific Goldberg deposits pyrrolidone onto siloxane substrate materials.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener
March 25, 2002



MICHAEL BARR
PRIMARY EXAMINER